REMARKS

The Examination

Independent claims 1, 19, and 25 were objected to because of various informalities. We have amended these claims accordingly.

Claims 14-17 were rejected under 35 U.S.C. Section 112 as being indefinite for failing to particularly point out and distinctly claim our invention. We have amended these claims accordingly.

Claims 1, 2, 6, 7, and 25 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent Number 5,309,916 to Hatsheck ('Hatsheck') in view of 5,025,791 to Niwa ('Niwa').

Claims 1, 2, 12-14, and 26 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent Number 5,140,990 to Jones et al. ('Jones') in view of Niwa.

Claims 3, 4, 11, and 16 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Jones in view of Niwa as applied to claims 1, 2, 12-14, and 26, and further in view of US Patent Number 5,368,026 to Swedlow et al. ('Swedlow').

Claim 5 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Hatscheck in view of Niwa, as applied to claims 1, 2, 6, 7 and 25, and further in view of US Patent Number 6,705,990 to Gallant et al. ('Gallant').

Claims 1, 2, 6, 7, 9, 12, and 14 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over US Patent Number 6,616,613 to Goodman et al. ('Goodman') in view of Niwa.

Claim 15 was rejected under 35 U.S.C. Section 103(a) as being unpatentable in view of Jones over Niwa as applied to claims 1, 2, 12-14 and 26 above, and further in view of Swedlow.

Claim 17 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Jones in view of Niwa and US Patent Number 5,995,857 as applied to claim 27 above, and in further view of Gallant.

Claim 19 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Hatscheck in view of Niwa, as applied to claims 1, 2, 6, 7 and 25 above and further in view of US Patent Number 6,475,153 to Khair et al. ('Khair').

Claim 27 was rejected under 35 U.S.C. Section 103(a) as being unpatentable over Jones in view of Niwa and in further view of US Patent Number 6,475,153 to Toomim et al. ('Toomim').

The Amended Claims

In order to more clearly describe the invention, we have amended independent claims 1, 12, 19, 25, and 26, along with dependant claims 14-17. With these amendments claims 1-7, 9, 11-17, 19, and 25-27 are pending in this Application.

The new amendments describe a blood pressure monitor that features a cuffless, optical measurement based on analysis of 'primary' and 'reflected' waves within an optical signal. The monitor is body-worn and measures blood pressure from an ambulatory user. The body-worn form factor, for example, is described in paragraphs [29] – [33] and Figs. 1, 1A, and 3. As described in our specification and below, the relative amplitudes of the primary and reflected waves are highly sensitive to blood pressure. Because this measurement is susceptible to motion-related artifacts that may distort or add noise to the waves, our microprocessor operates computer code that varies parameters of a mathematical model until they correspond to the amplitudes of the primary and reflective peaks. This is shown graphically, for example, in Fig. 4. To further combat motion-related artifacts, our invention includes a motion sensor (e.g. an accelerometer) that detects when an ambulatory user is at rest; this is the optimum time to make the blood pressure measurement.

Our specification clearly shows the efficacy of this approach with Figs. 4-6, Table 1, and related text in paragraphs [41] – [44]. These portions of the Application describe actual waveforms, containing both primary and reflected waves, collected from patients during clinical studies. Fig. 4 shows how the primary and reflected waves are analyzed (in this case 'fit') with a mathematical model to extract amplitude values for the primary and secondary waves. Fig. 5 shows waveforms measured at different blood pressures; the relative amplitudes of the primary and secondary waves in these waveforms are compared to blood pressure in Table 1. Finally, using this analysis, Fig. 6 shows a correlation between measured and calculated blood pressure using the above-mentioned approach. The relatively small error of the calculated measurement (3.2 mmHg for systolic; 1.9 mmHg for diastolic) indicates the efficacy of this approach.

With our new amendments, the independent claims now describe both a device and method for monitoring a user's blood pressure while the user is ambulatory. The device features a blood pressure sensor that includes a motion sensor configured to generate motion information from a user, and a blood pressure monitor comprising an optical system with both a light source and a light detector. The optical system generates a time-dependent waveform featuring a primary peak and a reflective wave that are, collectively, representative of the user's blood pressure. A cable connects the blood pressure monitor to a body-worn processing unit, which includes a microprocessor for receiving the time-dependent waveform from the blood pressure monitor and motion information from the motion sensor. Computer code controls the microprocessor to: 1) analyze both the primary and reflective waves comprised by the time-dependent waveform with a mathematical model by varying parameters of the model until they correspond to the amplitudes of the primary and reflective waves; 2) analyze the motion information to distinguish between time-dependent waveforms generated while the user is either moving or at rest; and 3) calculate a blood pressure value from parameters of the model determined from the time-dependent waveform generated when the user is at rest.

The Prior Art

The Examiner cited the following prior art references in the Office Action mailed October 18, 2006:

Hatscheck describes a device for measuring blood pressure that includes an optical sensor connected to an external display and monitoring device;

Niwa describes a reflectance pulse oximeter for measuring blood oxygenation that includes an accelerometer-based motion detector;

Jones describes a device for measuring blood pressure using an optical sensor that connects to an external computer;

Gallant describes an apparatus and method for monitoring plurality of physiological parameters, including blood pressure, which features a chair for the user and an external monitoring device;

Goodman describes a variety of blood pressure-monitoring devices, each featuring an optical sensor that measures an optical signal. A processor analyzes

the optical signal along with calibration information to determine blood pressure, which is then sent wirelessly to a computer system;

Swedlow describes a pulse oximeter that includes an accelerometer for measuring motion;

Toomin describes a method for measuring bio-feedback information from a patient's skull using, e.g., an optical source to estimate blood flow; and

Khair describes wrist-worn device for measuring blood pressure using an optical sensor array calibrated with a cuff-based measurement.

Patentability Over The Prior Art

The Examiner's primary references, Hatschek and Niwa, fail to describe our invention. Hatschek describes a time-domain approach to measuring blood pressure based on pulse wave velocity. This is fundamentally different than our approach, which analyzes the relative amplitudes of both primary and reflected waves by varying parameters of a mathematical model until they correspond to the amplitudes of these waves. Hatschek determines pulse wave velocity by measuring '[t]he time difference T_d between the two maxima 501a and 501c' which 'is a measure for the travel time of the reflected pulse waves and thus for the pulse wave velocity' (col. 23, lines 33-36). The Examiner's secondary reference, Niwa, only generically describes a 'pulse wave detecting apparatus', and thus falls far short of curing Hatschek's deficiencies for our blood pressure measurement.

Moreover, Hatschek's blood pressure monitor is aimed at measuring a stationary patient where motion-related artifacts are typically minimized. This means there is little need to combine a motion sensor, like that described in Niwa, with his invention. Just as importantly, Hatschek never describes motion-related artifacts as being a problem with his measurement, and thus provides the reader with no motivation to look elsewhere for such a sensor. Finally, because his monitor is not meant to be ambulatory, it is not worn on the patient's body:

> The two sensors 21, 23 of sensor means 13 are electrically connected by means of an electrical cable 35 with a display and monitoring unit or device 41 **disposed at a distance from the person being examined on a table or on the console of a bed frame**. The display and monitoring unit includes an instrument having a housing, but could also be constituted of

> several instruments in separate housings. (col. 10, lines 58-65; emphasis added)

In contrast, our invention is intended for ambulatory patients, and thus includes a body-worn processing unit and features a motion sensor to indicate when the patient is at rest. Thus even if Hatschek and Niwa are combined, which, based on the above, we believe can only be done with hindsight, the combination lacks all the features of our invention.

The Examiner's secondary references, Jones and Niwa, also fail to describe our invention. Jones describes a blood pressure-monitoring device that uses an optical system to measure a plethysmograph (i.e. an optical signal) from a patient's finger. The plethysmograph is combined with an external calibration (from, e.g., a conventional cuff) and processed with a mathematical equation to estimate blood pressure. But Jones's model is very different than that described in our claims. It relies on determining two primary properties – k and V_o/V_{inf} – by processing calibration information and the plethysmograph. Once determined, these properties are used in follow-on blood pressure measurements. k is a constant that relates to the patient's arterial pressure-volume relationship; it allows Jones to relate his optical signal, which as described in his patent relates to a change in volume in a measured artery, to the pressure in that artery. V_o is a voltage associated with the background of transmitted light (i.e., light that does not contribute to the AC portion of the plethysmograph), and V_{inf} is a voltage corresponding to the plethysmograph at infinite pressure. Neither of these properties relate to the amplitudes of the primary and reflected waves, as is required in our invention.

Its also important to note that while they do come from a mathematical equation, Jones's properties (k and V_o/V_{inf}) are not determined by 'fitting the waveform with a mathematical model', as the Examiner asserts, nor are they determined by varying parameters of a mathematical model. They are constants that are determined once during calibration, and then used in a follow-on analysis. So even if Jones is combined with Niwa, we believe the combined invention is much different than ours.

Moreover, we also believe that Jones, like Hatschek, is directed at a stationary blood pressure measurement, and not an ambulatory one. Thus, there is not a compelling reason to include complicated sensors for detecting motion in Jones's device. The patent, like Hatschek, makes no reference to motion or how this could be a problem during a blood pressure measurement. Thus, the reader finds no motivation to add a motion

sensor. And similar to Hatschek, Jones makes no reference to a body-worn processing unit, which is a critical component of our ambulatory measurement. Instead, the patent describes a 'computer' (24) and analog-to-digital converter (23) which appears to be external to the patient.

The Examiner's tertiary reference, Goodman, also fails to describe our invention when combined with Niwa. Goodman is similar to Hatschek in that his blood pressure measurement is based on pulse wave velocity calculated by taking a derivative of a plethysmograph. Pulse wave velocity is then used with a mathematic equation to calculate blood pressure:

> The characteristics of the aortic reflected wave are strong indicators of cardiovascular health. **The speed with which the aortic reflected wave travels along the aorta varies with changes in aortic compliance and blood pressure, both of which also affect aortic pulse wave velocity. The aortic reflected wave travels more quickly as blood pressure increases and as aortic compliance decreases.** It is also noteworthy that blood pressure and aortic pulse wave velocity rise and fall with respiration. Accordingly, by appropriately analyzing the aortic reflected wave, it is possible to obtain cardiovascular and respiratory information about an individual user, as will be discussed. (col. 15, lines 14-26; emphasis added)

Goodman goes on to describe approaches for determining blood pressure using pulse wave velocity, shown in Figs. 15C and 15D, described in corresponding text in col. 28, line 52 – col. 30, line 27, and indicated below. But despite these disclosures, Goodman fails to describe our fundamental method of calculating blood pressure, which relies on varying parameters of a mathematical model until they correspond to the amplitudes of the primary and reflective peaks. As described in detail above, this methodology is particularly well suited for ambulatory blood pressure measurements. So even if Goodman is combined with Niwa, the resultant combination still fails to include all the limitations of our amended claims.

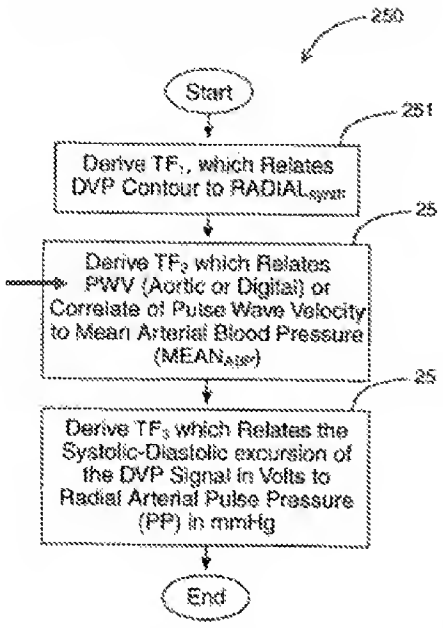

FIG. 15C

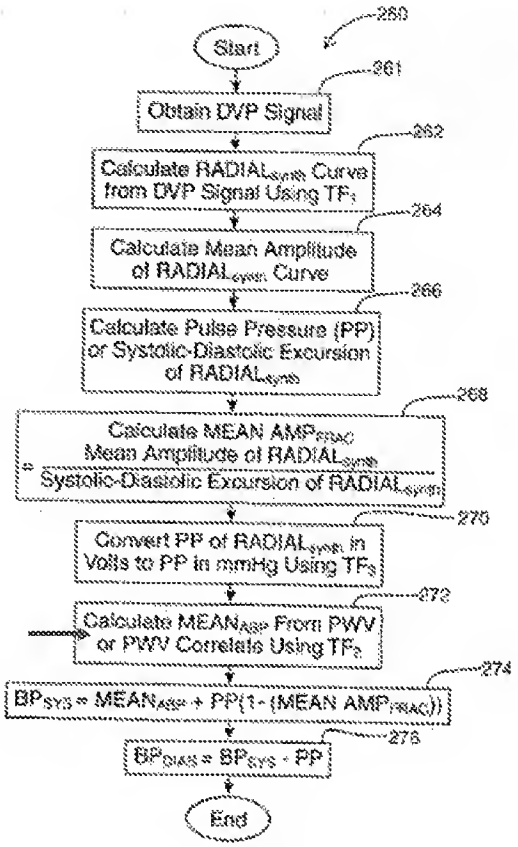

FIG. 15D

Figs. 15C and 15D - Goodman

The Examiner's other references each fail to describe our core technique for measuring blood pressure, and thus fail to cure the deficiencies of Hatschek, Jones, and Goodman, as described above. Swedlow, for example, only describes pulse oximetry and not blood pressure. Khair describes a blood pressure-measuring device that features a two-dimensional array of photodetectors to detect an optical image from a patient's underlying vasculature. The image is then compared to calibration information to estimate blood pressure. Gallant describes a tonometer-based blood pressure monitor that does not use an optical signal for determining blood pressure. Toomim is focused on a bio-feedback device, and provides no detail for blood pressure measurements.

Based on the above, we submit that the Examiner's references, even if combined, fail to teach all the limitations of the independent claims. The dependent claims are even further removed. We therefore respectfully ask the Examiner to issue a Notice of Allowance for this Application.

Respectfully Submitted,

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